**Exhibit 341** [replacing Dkt. #2357-6] attached to Plaintiffs' Consolidated Memorandum in Opposition to Defendants' Motions for Summary Judgment on Plaintiffs' Civil Conspiracy, RICO and OCPA Claims at Dkt. #2182.

• Redactions withdrawn by Defendant

## PSJ3 Exhibit 341

## RE: HDMA Regulatory Affairs Update

From:

"Ducca, Anita" <aducca@hdmanet.org>

To:

"Walker, Donald" <donald.walker@mckesson.com>

"Russell, Bruce" <bruce.russell@mckesson.com>, "Hilliard, Gary" <gary.hilliard@mckesson.com>, "Melville, Scott" <melville@hdmanet.org>

Date:

Tue, 05 Oct 2010 15:01:51 +0000

Don, I wanted to le you know that I received your e-mail. Thank you for getting back to me on this. I'll stay in touch on it.

From: Walker, Donald [mailto:Donald.Walker@McKesson.com]

Sent: Monday, October 04, 2010 5:49 PM

To: Ducca, Anita

Cc: Russell, Bruce; Hilliard, Gary

To: Regulatory Affairs Committee

Subject: RE: HDMA Regulatory Affairs Update

Anita, McKesson is not interested in meeting with GAO. The information we have already provided should be sufficient to get our views conveyed. Thank you for the followup and work in coordinating the response to GAO.

Don Walker

From: Ducca, Anita [mailto:aducca@hdmanet.org] Sent: Thursday, September 30, 2010 2:19 PM To: Ducca, Anita Subject: HDMA Regulatory Affairs Update

This e-mail is intended for HDMA Distributor members only. Please do not circulate it outside of your company's offices.

This is to provide you with several Regulatory Affairs Updates

- 1. FDA just issued a press release titled: FDA Orders Halt to Marketing of Unapproved Single-Ingredient Oral Colchicine. The link with further information is: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm227796.htm
- 2. We had a very worthwhile meeting with the GAO today. Although the officials we met with did not give much feedback, they were clearly interested in what we had to say about the lack of clarity and the expectations for wholesale distributors. Although they had sent us some questions, most of the discussion was about "suspicious orders" of controlled substances. I will schedule a call shortly to debrief you on the conversation.
- 3. GAO would like to know if any of our individual members are also interested in meeting with them to discuss DEA. If you are interested in meeting with them, please call or e-mail me to let me know so I can exchange the contact information. The underlying reason for the study is in their e-mail cut and pasted below. Their specific questions are also attached. I encourage your company to consider meeting with them.
  - a. They work to safeguard your anonymity
  - b. You can decline to answer any questions for any reason
  - c. Although we had a very productive meeting, some of the discussion was based on second hand information, so a more direct explanation of your experience could be beneficial
  - d. GAO had several questions that we could not answer (e.g., experience with DEA audits). We think it would be worthwhile to talk to them if you can share any information on such questions.
- 4. The regularly scheduled conference call next Thursday 10/7 is cancelled due to conflicts. I'll be in touch to schedule an alternative date.
- 5. If you haven't responded to the e-mail on the DOT rule, it's not too late. Please let me know if you're interested in being on a Task Force to respond to the proposal. Also,
  - a. I've spoken to several potential consultants/law firms with DOT experience and will be making a decision shortly.
  - b. I've sent the summary of potential issues to 11 trade associations. A few called me back for further information, and no one who responded had heard of the rule. A number of them did not respond at all. So I assume that they're not working on it. I have some additional follow-up calls to make so I'll let you know how that's going but I doubt that we can rely on anyone else to do the heavy lifting.
- 6. In case you have not already heard, HDMA discussed the response to FDA's REMS questions at the ExComm meeting last week. A copy was also forwarded to them electronically after the meeting with a request to respond to Scott Melville by the end of this week. Unless ExComm raises objections (by tomorrow), the document is ready for submission to FDA.

That's it for now. Please feel free to contact me if you have any questions.

Anita

Anita T. Ducca Senior Director, Regulatory Affairs Healthcare Distribution Management Association (HDMA) 901 North Glebe Rd., Suite 1000 Arlington, VA 22203 (703) 885-0240 Fax: (703) 812-5282 e-mail: aducca@hdmanet.org www.HealthcareDistribution.org Sent: Tuesday, September 07, 2010 6:10 PM

To: Ducca, Anita

Subject: GAO Review of DEA's Diversion Control Program

I am a senior analyst with the U.S. Government Accountability Office (GAO) working on a review of prescription drug diversion and the Drug Enforcement Administration's (DEA) efforts to combat this problem through its diversion control program. As you may already know, GAO is

## Case: 1:17-md-02804-DAP Doc #: 2841-46 Filed: 10/17/19 4 of 4. PageID #: 427493

the audit agency of the U.S. Congress that supports the Congress in meeting its oversight responsibilities and helps to improve the performance and accountability of the federal government. This request to look at DEA's diversion control program was made by the House Appropriations Subcommittee on Commerce, Justice, Science, and Related Agencies. The objectives for this review include: (1) How does DEA, along with state partners, ensure that registered entities comply with the Controlled Substances Act's provisions and implementing regulations and decide what registrants warrant further investigation? (2) To what extent does DEA ensure its employees follow DEA policies and procedures for diversion investigations? and (3) How does DEA, in partnership with the U.S. Attorneys Office, determine what penalties to apply in cases of non-compliance?

Based on the information on your website, we understand that the Healthcare Distribution Management Association (HDMA) represents distributors regulated by DEA under the Controlled Substances Act. As part of our work for this review, we would like to touch base with associations such as yours to get industry input and perspectives on DEA's diversion control efforts. We would greatly appreciate any information or input HDMA could provide on this issue. If possible, we would like to meet to discuss HDMA's perspectives on the current state of prescription drug diversion and DEA's efforts to address diversion.

If you have any information you would like to share or would be interested in meeting with us, please drop me a line here or give me a call. Of course, if you have any questions about this review, please also feel free to send me an email or give me a call.

Thank you,

Chris Hatscher